Dynavax Announces Exercise of Option to Reserve Additional CpG 1018 to Produce 40 Million Doses of Valneva’s Inactivated, Adjuvanted COVID-19 Vaccine Candidate for the UK Government

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EMERYVILLE, Calif., Feb. 1, 2021 /PRNewswire/ -- Dynavax Technologies Corporation (Nasdaq: DVAX), a biopharmaceutical company focused on developing and commercializing novel vaccines, today announced Valneva SE has informed it that the UK Government exercised its option to order an additional 40 million doses of Valneva’s SARS-CoV-2 adjuvanted vaccine candidate, VLA2001. This option exercise triggers the reservation of additional quantities of Dynavax’s advanced adjuvant CpG 1018 to support production of 40 million doses of Valneva’s SARS-CoV-2 adjuvanted vaccine candidate, VLA2001. In connection with its contract with the UK Government, Valneva has now reserved for delivery in 2021 CpG 1018 in quantities sufficient to support production of 100 million doses of VLA2001.

In September 2020, the companies announced a commercial partnership for the supply of Dynavax’s CpG 1018 adjuvant for use in VLA2001, to support Valneva’s agreement with the U.K. government to provide up to 190 million doses of VLA2001 over a five-year period. Dynavax expects to supply CpG 1018 to produce up to 100 million doses of vaccine in 2021. Valneva has the option to purchase additional quantities of CpG 1018 to support the production of up to an additional 90 million doses of VLA2001 through 2025.

“Our commercial supply agreement with Valneva substantiates our strategy of leveraging CpG 1018 as an advanced vaccine adjuvant for use in the development of safe and effective vaccines, including against COVID-19,” commented Ryan Spencer, Chief Executive Officer of Dynavax. “Under this agreement, we are currently manufacturing, and scheduled to deliver, adjuvant for 100 million doses of VLA2001 which would generate CpG 1018 revenue of up to $230 million in 2021, contingent on delivery of material and the continued success of the program. We believe the emerging portfolio of CpG 1018 opportunities has the potential to drive the next leg of Dynavax growth, adding to the substantial opportunity of HEPLISAV-B, our U.S. FDA approved adult hepatitis B vaccine.”

This commercial supply partnership follows Valneva and Dynavax’s initial collaboration to advance COVID-19 vaccine development, announced in April 2020. VLA2001 entered Phase 1/2 clinical studies in December 2020 and has recently completed enrollment. Initial safety and immunogenicity data are expected in April 2021.

About CpG 1018 Adjuvant
CpG 1018 is the adjuvant used in HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], an adult hepatitis B vaccine approved by the U.S. Food and Drug Administration (FDA). Dynavax developed CpG 1018 to provide an increased vaccine immune response, which has been demonstrated in HEPLISAV-B. CpG 1018 provides a well-developed technology and a significant safety database, potentially accelerating the development and large-scale manufacturing of a COVID-19 vaccine.

About Dynavax
Dynavax is a commercial stage biopharmaceutical company developing and commercializing novel vaccines. The Company launched its first commercial product, HEPLISAV-B® [Hepatitis B Vaccine (Recombinant), Adjuvanted], in February 2018, following U.S. FDA approval for prevention of infection caused by all known subtypes of hepatitis B virus in adults age 18 years and older. Dynavax is also further developing CpG 1018 as an advanced vaccine adjuvant through research collaborations and partnerships. Current collaborations are focused on adjuvanted vaccines for COVID-19, pertussis and universal influenza. For more information, visit www.dynavax.com and follow the company on LinkedIn.

Dynavax Forward-Looking Statements
This press release contains “forward-looking” statements, including statements regarding the potential development of a COVID-19 vaccine containing CpG 1018 and the commercial sale of CpG 1018 to be used in the vaccine. Actual results may differ materially from those set forth in this press release due to the risks and uncertainties inherent in vaccine research and development, including the timing of completing development, the results of clinical trials, whether and when the vaccine containing CpG 1018 will be approved for use, whether and when purchases of CpG 1018 will occur, and the ability to manufacture sufficient supply to meet the purchasing needs, as well as other risks detailed in the “Risk Factors” section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 as well as discussions of potential risks, uncertainties and other important factors in our other filings with the U.S. Securities and Exchange Commission. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. Information on Dynavax’s website at www.dynavax.com is not incorporated by reference in our current periodic reports with the SEC.

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